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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,196	05/24/2001	Kok-Hwee Ng	F4-5728 (1417P P 591)	2014

7590 10/20/2003

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EXAMINER	
SHAPIRO, JEFFERY A	

ART UNIT	PAPER NUMBER
3653	

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/865,196	TOD, JR., G. ROBERT16	
	Examiner	Art Unit	
	Jeffrey A. Shapiro	3653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 7/22/03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 4/28/01 has been reviewed and is NOT accepted.

The terminal disclaimer does not comply with 37 CFR 1.321(b) and/or (c) because:

The application/patent being disclaimed has not been identified. It appears that application 09/864,888 is not cited.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 58-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langley (US 233,525 B1) in view of Engleson et al (US 5,781,442). Langley discloses a system for monitoring and tracking at least a portion of a blood component collection procedure in a blood component facility, performed upon a donor by an operator, as follows.

As described in Claim 58;

1. a blood component collection instrument (18 and needle assembly, see col. 5, lines 28-30) for collecting a blood component from a donor;

2. the donor having a donor identifier (see col. 9, lines 22-41) and the blood component collection instrument having a blood collection instrument identifier (note that it would be expedient for one ordinarily skilled in the art to provide such an identifier—see Baluyot et al, figure 1 and col. 3, lines 34-41);

3. a blood component collection kit having a blood component collection kit identifier, the blood component collection kit for collecting the blood component from the donor; (Note that the blood collection kit includes a bag/container to store the blood in, which would be obvious to identify by one ordinarily skilled in the art with a particular patient/donor since the blood must be tracked from the donor to the patient to secure against problems with the blood based on the donor's health condition. See also Engleson et al which tracks consumables (140) (see col. 10, lines 55-67 of Engleson et al) and uses bar codes to identify a number of system variables, as shown in figures 4, 5, 5A and 6. *Note that blood components are construed as consumables as such blood products, for example, plasma, are routinely required for surgeries, etc. Note also col. 1, lines 47-51, which describes a blood sample being identified as being from a particular patient.*)

4. a central input station (computer (148), see col. 4, lines 44-50) being operably connected to the blood component collection instrument (see col. 4, lines 50-65), the central input station comprising a program having a plurality of code segments, at least one code segment monitoring operation of a blood component collection instrument and at least one other code segment tracking operation of the blood component collection instrument (see figure 5, noting "perform collection procedure" and "data transfer back to central station"—note also that the central input station can be considered to be a server, or at the very least, part of a network, as suggested by col. 13, lines 25-30—*see also figure 5, noting "transfer/download collection device controller" step*);

5. a memory operably connected to the system server, the memory for storing information received by the central input station (note that computers must have memory in order to store information—*note also that disk (142) of Langley stores information and is a form of memory—see also Engleson, col. 7, lines 41-43, which mentions storage of data in a CPU memory or on a disk*);

6. an interface operably connected to the system server, the interface having a display for monitoring the at least one portion of the blood component collection procedure (see figure 1, noting the computer (148) with display, keyboard and mouse);

As described in Claims 59 and 82;

7. a report comprising information from the memory, the information in the memory being selected from the group consisting of data blood component collection instrument data, operator data and donor data (note that Langley, col. 9, lines 42-61, for example, describe output which include such data, noting also that it would be expedient for one ordinarily skilled in the art to organize such data into an output such as a printed report);

As described in Claims 60 and 82;

8. the interface comprises a reader for entering information to be transmitted to the system server and received by the program for monitoring the blood collection kit, the blood component collection kit identifier being transmitted to the system server via the reader;

As described in Claim 61;

9. a blood component collection process number is associated with the blood component collection procedure, the donor, the blood collection kit and the blood collection instrument, wherein the interface transmits the donor identifier, the collection kit identifier and the blood component collection instrument identifier to the system server (See also Engleson et al which tracks consumables (140) and uses bar codes to identify a number of system variables, as shown in figures 4, 5, 5A and 6);

As described in Claim 62;

10. the interface is remotely located from the blood component collection instrument (note that the computer (148) is located at a point away from the blood collection instrument as shown in figure 1);

As described in Claim 63;

11. a blood component collection process number is associated with the blood component, and wherein the blood component collection instrument identifier, the blood donor identifier and the blood component collection process number are associated with the blood collection kit (See also Engleson et al which tracks consumables (140) and uses bar codes to identify a number of system variables, as shown in figures 4, 5, 5A and 6);

As described in Claim 64;

12. a label is created in response to a change of status of the blood component collection kit (see Beecham, US 5,897,989) which uses label device (24), noting that it would be expedient for one ordinarily skilled in the art to provide a label);

As described in Claim 65;

13. a blood collection kit inventory database, the blood collection kit inventory database operably connected to a blood collection kit supply wherein the blood collection kits can be replenished at the blood collection facility as needed (see Eagleson, col. 3, lines 12-20, which describes use

of an inventory database as part of a system for collecting patient data and managing patient care);

As described in Claim 66;

14. the program automatically updates the blood collection kit inventory database in response to the blood collection kit identifier being input into the interface (note that it would be obvious to one ordinarily skilled in the art to update the inventory database based upon removal or inclusion of blood collection kits, or other consumables such as needles, drugs, alcohol, swabs and bandages, for example);

As described in Claim 67;

15. a remote server operably connected to the system server via a communication network, the remote server monitoring and tracking a remote blood collection facility (note that Engleson et al also teaches use of a server based system, which one ordinarily skilled in the art would recognize as easily adaptable to be used with the system of Langley, so as to provide a full range of patient data information);

As described in Claim 68;

16. the interface comprises a screen menu for providing information about the blood collection kit (see Engleson, figures 7-12, noting that it would be expedient for one ordinarily skilled in the art to provide such data as part of the healthcare data information screens described and illustrated);

As described in Claims 69 and 82;

17. the interface comprises;

a. a reader (see Engleson, figure 2, element (69)) for entering information;

b. a transmitter for transmitting information to the server (note that the bar code reader and printer are connected by wire to the pharmacy CPU (60));

As described in Claims 70 and 82;

18. a receiver (See Engleson (40)) for receiving information from the server;

19. a web browser cooperating with the server, the web browser for displaying information saved in the memory; (See Engleson, noting that the web browser is shown in figures 7-12 and

As described in Claim 70;

20. the interface utilizes radio frequency (see Engleson, col. 3, lines 21-24) to transmit to the system server;

As described in Claim 71;

21. the reader comprises a touch pad (see Engleson, figure 2, element (73) for entering information into the program;

As described in Claim 72;

22. the reader comprises a touch pad for entering information into the program (note that a touch pad is a functional equivalent of a touch screen);

As described in Claim 73;

23. the interface comprises a stylus for cooperating with the touch pad wherein written text can be entered (note that a stylus is a functional equivalent of a touch screen);

As described in Claim 74;

24. the reader comprises a keypad for entering information into the program (see either Engleson or Langley);

As described in Claim 75;

25. the reader comprises an optical scanner for entering information into the program (note that bar code reader of Engleson (69) is such a scanner);

As described in Claim 76;

26. the reader comprises a magnetic scanner for entering information into the program (note that this is a functional equivalent of a bar code reader);

As described in Claim 77;

27. the interface comprises a menu for monitoring the at least one portion of the blood component collection procedure (see Engleson

menus, figures 7-12, noting that it would be expedient to provide such capabilities in the menus of Engleson);

As described in Claim 78;

28. the interface comprises a menu for tracking the at least one portion of the blood component collection procedure (see Engleson menus, figures 7-12, noting that it would be expedient to provide such capabilities in the menus of Engleson);

As described in Claim 79;

29. a communication conduit operably connecting the blood component collection instrument to the system server (note that a wire is a communication conduit, which both Langley and Engleson et al use throughout their systems); and

30. a web interface being operably connected to the system server, the web interface providing access to the system server for monitoring the at least one portion of the blood component collection procedure (see Engleson menus, figures 7-12, noting that it would be expedient to provide such capabilities in the menus of Engleson);

As described in Claim 80;

31. the communication conduit utilizes Ethernet (see col 4, line 37 of Engleson);

As described in Claim 81;

32. wherein the communication conduit utilizes TCP/IP (note that it would be expedient for one ordinarily skilled in the art to use such a protocol, especially, for a network which would use the internet);

As described in Claim 83;

33. a fifth segment of the computer readable medium for determining eligibility of the donor (note that it is well known that blood screening is used by the red cross to screen for items such as hepatitis or HIV—see Quattrocchi (US 5,978,466) which describes a method for testing for HIV, as well as another system which tracks a blood component sample, kit and donor/patient);

As described in Claim 84;

34. a sixth segment for generating a bleed number (see Baluyot et al, lines 6-40);

35. a seventh segment for linking the blood component collection instrument to the bleed number (see also Engleson et al which tracks consumables (140) and uses bar codes to identify a number of system variables, as shown in figures 4, 5, 5A and 6.), noting that it would be expedient to identify and link any number of variables and items required in such a procedure as taking blood);

36. an eighth segment for linking the donor to the bleed number;

As described in Claim 85;

37. a ninth segment for monitoring the at least a portion of the blood component collection procedure by utilizing the information received from the blood component collection instrument (see previous);

As described in Claim 86;

38. a tenth segment for reading a blood component collection kit identifier associated with a blood component collection kit;

39. an eleventh segment for storing the blood component collection kit identifier in the system server; and

40. a twelfth segment for linking the blood component collection kit with the bleed number;

(note again that Engleson et al provides a bar code reader and bar code labels, which one ordinarily skilled in the art would find expedient to place on any part of the system required to identify it to said system)

As described in Claim 87;

41. a thirteenth segment for generating a report utilizing the information received from the blood component collection instrument (note again that report generation would have been expedient to one ordinarily skilled in the art);

As described in Claim 88;

42. a fourteenth segment for generating a report in utilizing the information received from the interface (note again that report generation would have been expedient to one ordinarily skilled in the art);

Both Langley and Engleson are considered to be analogous art because Engleson describes a patient information collection, tracking and monitoring system and Langley describes a blood component collection device which compiles information about the blood component collection process.

At the time of the invention, it would have been expedient to use the system of Langley with the system of Engleson, marrying them up so as to work in concert with each other.

The suggestion/motivation would have been to provide information about the blood collection process to a complete patient data collection and management system. This would better provide a way to control healthcare costs, among other things as well as to provide more complete data for bio-emergencies such as disease outbreaks which might affect the blood supply as well as blood usage problems which might strain the blood component supply system.

Therefore, it would have been obvious to combine Engleson and Langley in order to obtain the system described in Claims 58-88.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 58-88 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/864,888 in view of Engleson.

This is a provisional obviousness-type double patenting rejection.

6. Claims 58-88 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/865,052 in view of Engleson.

This is a provisional obviousness-type double patenting rejection.

7. Claims 58-88 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/864,926 in view of Engleson.

This is a provisional obviousness-type double patenting rejection

8. Claims 58-88 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/864,891 in view of Engleson.

This is a provisional obviousness-type double patenting rejection

Response to Arguments

2. Applicant's arguments filed 7/22/03 have been fully considered but they are not persuasive. Applicant asserts that Langley , Engleson and Baluyot do not disclose "a computer readable medium for use in connection with an operator interface for

monitoring and tracking at least a portion of a blood component collection procedure in a blood component collection facility, performed upon a donor, the medium comprising: a first segment for reading information from a blood component collection instrument, and a second segment for storing information from the blood component collection instrument in a system server. " Applicant further asserts that Langley and Engleson do not apply to the instant claims because Langley concerns a blood component collection system utilizing a prediction model for plasma-related values, and Engleson discloses the monitoring of infusion pumps.

This is incorrect. Langley and Engleson, although they do disclose the apparatus and systems with these functions, they also disclose other functions which directly concern Applicant's claimed limitations.

Langley, as described above, does disclose a blood component collection facility, the collection being performed on a donor. Langley also describes reading information from the blood collection apparatus. Again, see col. 9, lines 22-41, noting that plasma and platelets are considered components of blood, and indicates that analysis of a blood sample from the donor is directly fed to the system, including cell count. Note also that the prediction model provides platelet collection efficiency and effective procedure time (see col. 10, lines 11 and 31). Even though an equation is used to process information from the blood collection process, parameters from the process in the form of raw data used in the equation do not change the fact that such data is a direct measure of the blood collection process.

Although Engleson concerns control of an infusion pump, it does not change the fact that Engleson discloses the tracking system described above. In fact, control of the infusion pump can be construed as controlling the collection instrument.

Baluyot et al is only cited as an example of the use of barcode identifiers for linking the sample containers, the collection instrument, and the bleed number, again, as described above.

Therefore, as Applicant's independent claims, as currently written, and reasonably broadly construed, read on the prior art, as described above, the rejection is maintained.

Note also that Applicant does not appear to respond to the double patenting rejections over Application No. 09/865,052 in view of Engleson, Application No. 09/864,926 in view of Engleson, and Application No. 09/864,891 in view of Engleson.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey A. Shapiro whose telephone number is (703)308-3423. The examiner can normally be reached on Monday-Friday, 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald P. Walsh can be reached on (703)306-4173. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1113.

Jeffrey A. Shapiro
Examiner
Art Unit 3653

October 16, 2003

DONALD P. WALSH
SUPERVISORY PATENT EXAMINER
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